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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,804	11/10/2005	Magali Williamson	620-373	4496

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EXAMINER	
REDDIG, PETER J	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
11/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,804	WILLIAMSON ET AL.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *May 27, 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *76-114* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *76-114* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 76-86, drawn to a method of assessing an individual for a cancer condition comprising; providing a tissue sample obtained from said individual, determining the presence in said sample of one or more cells comprising a plexinB1 nucleic acid sequence having one or more mutations in a coding region of said plexinB1 nucleic acid sequence, the presence of said one or more cells being indicative of said individual having a cancer condition.

Group 2, claim(s) 87-95, drawn to a method of determining the invasiveness of a cancer cell in a sample obtained from an individual, the method comprising, determining the presence or absence in said cell of a plexin B1 polypeptide having one or more mutations therein, the presence of said plexin B1 polypeptide being indicative that the cell is invasive.

Group 3, claim(s) 96-105 and 112, drawn to a method of identifying and/or obtaining a putative anti-cancer agent, the method comprising; contacting a plexinB1 polypeptide with a test compound, wherein the plexinB1 polypeptide comprises one or more mutations, and; determining the activity of the plexinB1 polypeptide in the presence relative to the absence of test compound.

Group 4, claim(s) 106-111, drawn to a method of identifying and/or obtaining a compound as a putative anti-cancer agent, the method comprising; contacting a plexinB1 nucleic acid with a test compound, wherein the plexinB1 nucleic acid comprises one or more mutations in a coding region of the nucleic acid, and; determining the expression of the plexinB1 nucleic acid in the presence relative to the absence of test compound.

Group 5, claim(s) 113, drawn to a method of screening for an antibody molecule specific for a mutant plexinB1, the method comprising; providing a population of antibody molecules specific for mutant plexinB1, contacting said population with a normal plexinB1 polypeptide, identifying one or more members of said population which bind preferentially to mutant plexinB1 relative to normal plexinB1.

Group 6, claim(s) 114, drawn to an antibody molecule which specifically binds to a mutant plexinB1 polypeptide.

An international stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. The inventions listed as Groups 1-6 do not relate to a single general inventive concept under PCT Rule 13.1 because unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

A) A product and a special process of manufacture of said product.

B) A product and a process of use of said product.

C) A product, a special process of manufacture of said product, and a process of use of said product.

D) A process and an apparatus specially designed to carry out said process.

E) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The inventions of groups 1-6 are drawn to a product as well as multiple methods of using said product or a different product. Allowed combinations do not include a product as well as multiple methods of using said product or a different product, as claimed in the instant application. Hence, only one product and one process of use of said product relate to a single general inventive concept. Since a product as well as multiple methods of using said product or a different product with different special technical features are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d). Group 1 will be the

main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Group 1 is drawn to a process of use of said product.

Groups 2-5 are additional methods of using said product or different products.

Group 6 is the product.

Accordingly, Groups 1-6 are not so linked as to form a single general inventive concept and the finding of lack of unity is proper.

Applicant is advised that the reply to this restriction requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Species Elections for Group 1

A. Claim 76 is generic to the following disclosed patentably distinct species of methods of determining the presence of a plexin B1 nucleic acid sequence having one or more mutations in a coding region:

1) at the nucleic acid level

2) at the protein level

B. Claim 76 is generic to the following disclosed patentably distinct species of one or mutation sites:

T1697, T1733, T1776, T1795, T1802, P1597, P1798, F1711, G1602, L1815, N1735, R1904, A1730, G1728, and K1613.

Applicants must elect one or a specific, defined combination of mutation sites that is supported in the specification.

C. Claim 76 is generic to the following disclosed patentably distinct species of mutations:

T1697A, T1733I, T1776A, T1795A, T1802A, P1597L, P1597S, P1798S, F1711I, G1602T, L1815P, N1735S, R1904W, A1730T, G1728S, L1815F, and K1613E.

Applicants must elect one or a specific, defined combination of mutations that is supported in the specification.

Species Elections for Group 2

A. Claim 87 is generic to the following disclosed patentably distinct species of methods of determining the presence of a mutant plexin B1 polypeptide:

1) at the nucleic acid level

2) at the protein level

B. Claim 87 is generic to the following disclosed patentably distinct species of one or mutation sites:

T1697, T1733, T1776, T1795, T1802, P1597, P1798, F1711, G1602, L1815, N1735, R1904, A1730, G1728, and K1613.

Applicants must elect one or a specific, defined combination of mutation sites that is supported in the specification.

C. Claim 87 is generic to the following disclosed patentably distinct species of mutations:

T1697A, T1733I, T1776A, T1795A, T1802A, P1597L, P1597S, P1798S, F1711I, G1602T, L1815P, N1735S, R1904W, A1730T, G1728S, L1815F, and K1613E.

Applicants must elect one or a specific, defined combination of mutations that is supported in the specification.

Species Elections for Group 3

A. Claim 96 is generic to the following disclosed patentably distinct species of one or mutation sites:

T1697, T1733, T1776, T1795, T1802, P1597, P1798, F1711, G1602, L1815, N1735, R1904, A1730, G1728, and K1613.

Applicants must elect one or a specific, defined combination of mutation sites that is supported in the specification.

B. Claim 96 is generic to the following disclosed patentably distinct species of one or more mutations:

T1697A, T1733I, T1776A, T1795A, T1802A, P1597L, P1597S, P1798S, F1711I, G1602T, L1815P, N1735S, R1904W, A1730T, G1728S, L1815F, and K1613E.

Applicants must elect one or a specific, defined combination of mutations that is supported in the specification.

A. Claim 96 is generic to the following disclosed patentably distinct species of one or more activity assays:

1) binding of said polypeptide to semaphorin4D

2) binding of said polypeptide to active Rac1

3) binding of said polypeptide to Met

4) binding of said polypeptide to PDZ-RhoGEF

5) binding of said polypeptide to LARG

6) binding of said polypeptide to components of the semaphorin signaling pathway interacting with plexinB1, other than those listed above

Applicants must elect one or a specific, defined combination of proteins to be bound that is supported in the specification.

Species Elections for Group 4

A. Claim 106 is generic to the following disclosed patentably distinct species of one or mutation sites of the plexin coding sequence:

5059, 5060, 5074, 5107, 5359, 5401, 5452, 5458, 5468, 5474, 5596, 5653, 5662, 5674, 5713, 5714, and 5980

Applicants must elect one or a specific, defined combination of mutation sites that is supported in the specification.

B. Claim 106 is generic to the following disclosed patentably distinct species of one or more mutations:

C5059T, C5060T, G5074A, A5107G, A5359G, T5401A, G5452A, G5458A, C5468T, A5474G, A5596G, A5653G, C5662T, A5674G, C5713T, T5714C and C5980T.

Applicants must elect one or a specific, defined combination of mutations that is supported in the specification.

Species Elections for Group 5

A. Claim 113 is generic to the following disclosed patentably distinct species of one or mutation sites as contemplated in the specification:

T1697, T1733, T1776, T1795, T1802, P1597, P1798, F1711, G1602, L1815, N1735, R1904, A1730, G1728, and K1613.

Applicants must elect one or a specific, defined combination of mutation sites that is supported in the specification.

B. Claim 113 is generic to the following disclosed patentably distinct species of one or more mutations as contemplated in the specification:

T1697A, T1733I, T1776A, T1795A, T1802A, P1597L, P1597S, P1798S, F1711I, G1602T, L1815P, N1735S, R1904W, A1730T, G1728S, L1815F, and K1613E.

Applicants must elect one or a specific, defined combination of mutations that is supported in the specification.

Species Elections for Group 6

A. Claim 114 is generic to the following disclosed patentably distinct species of one or mutation sites as contemplated in the specification:

T1697, T1733, T1776, T1795, T1802, P1597, P1798, F1711, G1602, L1815, N1735, R1904, A1730, G1728, and K1613.

Applicants must elect one or a specific, defined combination of mutation sites that is supported in the specification.

B. Claim 114 is generic to the following disclosed patentably distinct species of one or more mutations as contemplated in the specification:

T1697A, T1733I, T1776A, T1795A, T1802A, P1597L, P1597S, P1798S, F1711I, G1602T, L1815P, N1735S, R1904W, A1730T, G1728S, L1815F, and K1613E.

Applicants must elect one or a specific, defined combination of mutations that is supported in the specification.

In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a

common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 USC 103. Since the decisions in *In re Weber*, 198 USPQ 328 (CCPA 1978) and *In re Hass*, 198 USPQ 334 (CCPA 1978), it is proper for the Office to refuse to examine that which applicants regard as their invention, if the subject matter in a claim lacks unity of invention, see MPEP 803.02.

The above species are independent or distinct because they comprise structurally distinct molecules and have different modes of operation and different effects. Further, each species would require different searches and the consideration of different patentability issues.

Further some of the species are related as combination and subcombination. Species in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations is useful for screening for different variables and different markers. Thus the claims are distinct as required by MPEP 806.05(c).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each species group above for the elected invention Group, even though this requirement is traversed.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Effective November 1, 2007, if applicant wishes to present more than 5 independent claims or more than 25 total claims in an application, applicant will be required to file an examination support document (ESD) in compliance with 37 CFR 1.265 before the first Office action on the merits (hereafter "5/25 claim threshold"). See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46715 (Aug. 21, 2007), 1322 Off. Gaz. Pat. Office 76 (Sept. 11, 2007) (final rule). The changes to 37 CFR 1.75(b) apply to any

pending applications in which a first Office action on the merits (FAOM) has not been mailed before November 1, 2007. Withdrawn claims will not be taken into account in determining whether an application exceeds the 5/25 claim threshold. For more information on the final rule, please see http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html.

In response to the restriction requirement set forth in this Office action, applicant is required to file an election responsive to the restriction requirement. Applicant may not file a suggested restriction requirement (SRR) in lieu of an election responsive to the restriction requirement as a reply. A SRR alone will not be considered a *bona-fide* reply to this Office action.

If applicant elects an invention that is drawn to no more than 5 independent claims and no more than 25 total claims, applicant will not be required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims. If the elected invention is drawn to more than 5 independent claims or more than 25 total claims, applicant may file an amendment canceling a number of elected claims so that the elected invention would be drawn to no more than 5 independent claims and no more than 25 total claims.

If the restriction requirement is mailed on or after November 1, 2007, applicant is also required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims, unless the elected invention is drawn to no more than 5 independent claims and no more than 25 total claims taking into account any amendment to the claims. To avoid the abandonment of the application, the ESD (if required) and the election must be filed within **TWO MONTHS** from

the mailing date of this Office action. The two-month time period for reply is extendable under 37 CFR 1.136.

If the restriction requirement is mailed before November 1, 2007, the election must be filed within **ONE MONTH** or THIRTY DAYS, whichever is longer, from the mailing date of this Office action. The time period for reply is extendable under 37 CFR 1.136. Furthermore, if the elected invention is drawn to more than 5 independent claims or more than 25 total claims taking into account any amendment to the claims, the Office will notify applicant and provide a time period in which applicant is required to file an ESD in compliance with 37 CFR 1.265 covering each of the elected claims or amend the application to contain no more than 5 independent elected claims and no more than 25 total elected claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

Signature on Previous Page

Peter J. Reddig
Examiner
Art Unit 1642

PJR